DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 20,2014

CareFusion
c/o Mark Job
Regulatory Technology Services LLC
1394 25th Street N.W.
Buffalo, Minnesota 55313

Re: K143234
Trade/Device Name: MaxZero Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FPA
Dated: November 7, 2014
Received: November 10, 2014

Dear Mark Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA

Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143234

Device Name
MaxZero Administration Sets

Indications for Use *(Describe)*

The MaxZero Intravascular Administration set with needleless connector(s) is a device used to administer fluids from a container to a patient's vascular system. The administration set is for single patient use only. The administration set can be used for direct injection, intermittent infusion or continuous infusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K143234

Submitter Information

A. Company Name: CareFusion
B. Company Address: 10020 Pacific Mesa Blvd.
San Diego, CA 92121
C. Company Phone: (858) 617-3042
D. Company Fax: (858) 617-5982
E. Contact Person: Larry Walker
F. Date Summary Prepared: October 14, 2014

Device Identification

A. Trade Name MaxZero Administration Sets
B. Common Name: IV Administration Sets
C. Classification: IV Administration Set, Needleless Connector, Closed Access, 21 CFR 880.5440, (Product code FPA)

Legally Marketed Predicate Device for Substantial Equivalence

Predicate Device	Manufacturer	510(k) #	Date Cleared
(Primary) Medegen Intravascular Administration Set and Extension Set	CareFusion (formerly Medegen)	K051499	June 22, 2005
MZ1000 Needleless Connector	CareFusion	K132413	August 29, 2013

Rational for Substantial Equivalence

The information provided in the premarket notification demonstrates that the subject CareFusion MaxZero Administration Sets are substantially equivalent to the legally marketed predicated devices. The subject MaxZero Administration Sets and the primary predicate Medegen Administration Sets are intended to be used for the delivery of fluids to an IV catheter in a hospital environment. The subject and the predicate devices are similar in physical properties, materials, and configuration. Each device includes connectors that allow for needleless access to the IV line during IV therapy eliminating the risk of needle injury. The subject device incorporates the predicate MZ1000 Needleless Connector bonded directly to IV tubing. Components of the subject devices are made of materials that are substantial equivalent to the predicate devices listed above and this submission includes comprehensive biocompatibility testing for all device materials included in this submission.

Device Description

The CareFusion MaxZero Administration Sets are intravascular administration sets intended for single patient use, including pediatrics and immunocompromised patients, for direct

injection, intermittent infusion continuous infusion of drugs, blood and fluids. All MaxZero Administration Sets include the previously cleared zero reflux MZ1000 Needleless Connector (K132413) bonded to the extension set tubing. The MZ1000 needleless connector allows thorough and easy disinfection due to a solid, flat smooth surface and eliminates the risk of needlestick injuries. The MaxZero Administration Sets are sterile single patient devices. All extension sets included in this submission are not made from material containing natural rubber latex or DEHP.

The following model numbers are subject to this submission:

Model Number	Description	Tubing ID	Tubing OD
MZXT4001	MaxZero administration set, microbore tubing, amber tubing, IV connector, 20 drop drip chamber, filter, check valve, T-connector, ≈95 inch l	0.020"	0.079"
MZ8001	MaxZero Administration set, microbore tubing, 3 MaxZero connectors, 20 drop drip chamber, 0.2 micron filter, check valve, anti-siphon valve, 3 colored pinch clamps, spin male luer. ≈ 95 inches	0.020"	0.079"

Intended Use

The MaxZero intravascular administration set with needleless connector(s) is a device used to administer fluids from a container to a patient's vascular system. The administration set is for single patient use only. The administration set can be used for direct injection, intermittent infusion or continuous infusion.

Substantial Equivalence Table

Device	CareFusion MaxZero Administration Sets	CareFusion (formerly Medegen) Intravascular Administration Set and Extension Set
510(k) #	TBD Subject device	K051499
Fluid contacting materials	**Needleless Connector:** Polycarbonate, silicone rubber **Drip Chamber:** PVC, ABS Polyethylene, Gelman Vespar **Tubing:** PVC **Bi-F Connector:** Rigid PVC **Back Check Valve:** MABS, silicon rubber **Male Luer Adapter**: ABS **Male Spinloc:** ABS **Female Luer:** Copolyester **Filter:** Acrylic, Gulman Supor	**Needleless Connector:** Polycarbonate. Liquid silicone rubber **Drip Chamber:** ABS, Polyethylene, PTFE **Tubing:** PVC **Rotating luer lock:** ABS **Female luer lock:** Copolyester **Male luer lock:** Acrylic **Bi-F Connector:** ABS **Check Valve:** ABS, silicone rubber **Stopcock:** Polycarbonate **Flow Controller:** ABS, silicon rubber **Manifold:** ABS, LDPE, silicon rubber, Copolyester **Filter:** Acrylic, Gore-Tex
Needleless Connector	CareFusion MZ1000 (K132413)	CareFusion NAC Plus Needleless Connector (K011193)
Functional Use	Direct Injection, intermittent infusion, continuous infusion	Direct Injection, intermittent infusion, continuous infusion, aspiration
Packaging	Tyvek/polymer pouch	Tyvek/ polymer pouch
Sterilization Method	E-Beam	Irradiation
Usable Life	Per facility protocol or in accordance with current recognized guidelines for IV therapy.	Per CDC guidelines

Technical Characteristics

Technological Characteristics
Zero Reflux Needleless Connector
Designed to prevent microbial ingress
Needleless connector can be disinfected with 3 sec scrub with 70% IPA
Non-hemolytic
Not made with DEHP
Safe for use in MRI environment
Not made with natural latex rubber
Sets can be used with harsh infusates

Clinical Data

There is no clinical data included in this submission.

Non-Clinical Data

CareFusion performed design verification performance testing to verify, demonstrate and support the claim of substantial equivalence to the predicate devices. All test results met their acceptance criteria and support that the MaxZero Administration Sets are appropriately designed for their intended use.

Testing performed included:

- Microbial ingress and barrier testing
- Design verification testing
- Shelf life performance testing
- Harsh Infusates testing
- Priming volume/flow rate testing
- Biocompatibility
- Sterilization

For complete list of non-clinical testing please see the following sections.

- Sterilization: Section 14
- Biocompatibility: Section 15
- Performance Bench: Section 18

Conclusion

The results of the non-clinical testing exhibited that no new issues of safety and efficacy are raised with the proposed introduction of the MaxZero Administration Sets. The device met the acceptance criteria for all functional, microbial ingress, sterility, biocompatibility and other performance criteria, which verify it to be substantially equivalent to the predicate devices. The conclusion drawn from the performance testing demonstrate that the CareFusion MaxZero Administration Sets are as safe as effective and performs at least as safe and effectively as the legally marketed predicate devices.